UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
COOKEVILLE DIVISION

ANDREW SCOTT RODRIGUEZ,	)	
	)	
Plaintiff,	)	**Case No. 2:08–0124**
	)	**Judge Trauger**
v.	)	
	)	
STRYKER CORPORATION and STRYKER SALES CORPORATION,	)	
	)	
Defendants.	)	

MEMORANDUM

Pending before the court is a Motion for Summary Judgment filed by defendants Stryker Corporation and Stryker Sales Corporation (Docket No. 109), to which the plaintiff has responded (Docket No. 152), and the defendant has filed a reply in support (Docket No. 174).[1] For the reasons discussed herein, this motion will be granted, and this case will be dismissed. The defendant also has filed ten motions seeking the exclusion or limitation of various expert testimony offered by the plaintiff. (Docket Nos. 99, 107, 113, 119, 122, 123, 127, 130, 132, and 135.) These motions have been fully briefed. As the court would grant Stryker's summary judgment motion regardless of the expert motions, these motions will all be denied as moot.[2]

RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

[1]While there are technically two defendants, throughout the briefing, they have been collectively referred to as "Stryker," and, for purposes of convenience, the court will refer to "Stryker" as the "defendant."

[2]This is not to say that the parties' exhaustive briefing on these motions was for naught. The court reviewed the materials and arguments provided by the parties, and these materials generally enhanced the court's familiarity with the complex medical issues involved in this case.

A. The Plaintiff's Surgery and Subsequent Ailment

On November 15, 2004, the plaintiff, Andrew Scott Rodriguez, underwent shoulder surgery at Vanderbilt Medical Center in Nashville, Tennessee.[3] At the conclusion of the surgery, the plaintiff's surgeon, Dr. John Kuhn, elected to control the plaintiff's post-operative pain with a pain pump – a prescription device that – over the course of about 48 hours – would steadily release local anesthetic (bupivacaine) into the area of the surgery.

Specifically, Dr. Kuhn implanted the catheter from a Stryker pain pump into the plaintiff's shoulder joint. While the surgery initially appeared to be a success, the plaintiff's shoulder pain around the operative site recurred, and, following another procedure on his shoulder in January 2008, the plaintiff learned that the cartilage in his shoulder joint was destroyed. In his December 30, 2008 Complaint, the plaintiff alleges that the cartilage degeneration in his shoulder results in extreme pain and was caused by the pain pump's constant delivery of the anesthetic following the 2004 surgery. (Docket No. 1 at 6.) The plaintiff maintains that he has developed a rare form of chondrolysis – a condition marked by the destruction of articular ("of the joint") cartilage.

The plaintiff's claims that Stryker is liable for his shoulder pain has raised interrelated issues of FDA compliance, the state of medical understanding at the time of the initial surgery, and Dr. Kuhn's interactions (or lack thereof) with Stryker, all of which are discussed herein.

B. The FDA Approval Process

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[3]Unless otherwise noted, the facts are drawn from the parties' statements of material facts (Docket Nos. 157 and 176) and related affidavits and exhibits. Although facts are drawn from submissions made by both parties, on a motion for summary judgment, all inferences are drawn in the light most favorable to the non-moving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S 574, 586 (1986); *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 800 (6th Cir. 2000).

The Food and Drug Administration (FDA) regulates medical devices such as the Stryker pain pump used during the plaintiff's November 2004 surgery for safety, effectiveness, and proper labeling. Prior to marketing a medical device, a drug manufacturer is required to obtain either Premarket Approval (PMA) or Premarket Notification, which is sought under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 360(k).

The requirement of obtaining FDA approval through either PMA or a 510(k) application applies both when a medical device is initially introduced into the commercial market and whenever a previously approved medical device is to be "significantly modified in . . . intended use." (Docket No. 176 at 3.) The parties agree that Section 510(k) is a significantly "less rigorous" option than PMA because Section 510(k) approval is awarded when the FDA deems a medical device "as safe and effective" as, or as substantially equivalent to, another legally marketed device. (*Id.* at 2.)

Continuous infusion pumps, in some form, have been used in medical practice since the 1960s. (Docket No. 116 Ex. F.) The Stryker Pain Pump I was originally developed by McKinley Medical in the late 1990s as the McKinley Outbound pain pump. In 1998, McKinley Medical filed a 510(k) notification with the FDA that requested approval to market the Outbound pain pump for use in the "synovial cavity," that is, the space in a joint, in addition to the already approved indications for the pump, which were intravenously, intra-arterially, and subcutaneously. (Docket No. 159 Ex. 4 at 7.) It appears that McKinley Medical withdrew its 510(k) request after the FDA noted that McKinley Medical could not come forward with a "legally marketed device" with the same indicated use, that is, another approved pain pump specifically indicated for use in the synovial cavity. (Docket No. 159 Ex. 5.)

On September 30, 1998, the FDA mistakenly granted McKinley's request to market the pain pump in the synovial cavity, concluding that there was a substantially equivalent, legally marketed product with this indicated use. (Docket No. 159 Ex. 8.) In a March 3, 1999 letter, the FDA self-identified its error, removing synovial cavity from the list of indications, maintaining the previous list of approved uses but also stating that the pump could be marketed for use with "a local anesthetic [infused] directly into the intraoperative site for postoperative pain management." (Docket No. 176 at 7.) There is no indication that McKinley sought further FDA approval for use of the pump specifically within the synovial cavity. In 1999, Stryker purchased the rights to the Outbound pump and renamed it the Pain Pump 1.0.

In 2000, Stryker filed a 510(k) notification with the FDA pertaining to the PainPump 2.0, again seeking FDA approval to market a pump for use in the synovial cavity. The Pain Pump 2.0 used a programmable computer, and it does not appear to be the pump that was used following the plaintiff's 2004 surgery. (Docket No. 110 at 4.) In June 2001, the FDA approved the 510(k) notification for the Pain Pump 2.0 and stated that "routes of administration [of pain medication] may be intraoperative, subcutaneous or percutaneous." (Docket No. 159 Ex. 19.) Again, under the less rigorous 510(k) procedure, the FDA did not explicitly approve the use of the pump in the synovial cavity. The June 2001 approval letter is a form letter that does not explicitly comment on the "synovial cavity" indication but simply approves the 510(k) request for "intraoperative, subcutaneous or percutaneous" use. (*Id.*)

There is no dispute that, from the time that the FDA initially cleared the products, Stryker's pain pumps have been cleared for "intraoperative" use. The instructions for use for each Stryker pain pump do not recommend any particular surgical procedure for which the pump

may be used, or any particular medication. There is essentially no dispute that, in the time prior to the plaintiff's November 2004 surgery (including the period after the FDA's denial of an indication for use in the synovial cavity), Stryker (1) conducted no meaningful testing or research into the risk of cartilage injury from use of the pump, (2) knew that the pumps were being widely used in the joint space following surgery, and (3) endorsed/did not discourage that use. Consistent with this, Stryker maintains that "intra-articular placement is included within the 'intraoperative site' category of approved indications." (Docket No. 176 at 21.)

C. Medical Understanding of the Risk of Cartilage Damage From Pain Pumps

In his trial testimony in a factually similar case[4], the plaintiff's general causation expert, Dr. Stephen Trippel, stated that, as of 2005, there were no case reports demonstrating that a patient had experienced cartilage damage from the administration of a local anesthetic by "any way or manner." (Docket No. 116 Ex. 9 at 3.) That said, there were some indications prior to 2005 that the "bathing" of the cartilage in "foreign objects" could cause damage.

The plaintiff brings forth a series of medical articles in support of his claims. The defendant does not challenge the content of the articles (although it raises a number of "stock" objections to the articles, including hearsay and relevance)[5], and the court will briefly summarize the plaintiff's (essentially undisputed) summary of the key articles:

– In 1933, Dr. J. Albert Key published an article "reporting that weak acids, alkalies, distilled water, and salt solutions are toxic to cartilage" and that multiple injections lead to cartilage damage. (Docket No. 176 at 27.)

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[4]There are approximately 200 similar "pain pump" cases being litigated around the country. (Docket No. 181 Ex. 2 at 2.)

[5]Although not the subject of any briefing, it appears that the articles would be admissible at trial under the "learned treatise" exception to the hearsay rule. *See* Fed. R. Evid. 803(18).

– In 1983, "the *Journal of Bone and Joint Surgery* published an article finding that saline solutions applied to [bovine] cartilage over a period of time, the longest being eight hours, inhibited cartilage health." (*Id.* at 28.)

– In 1985, "the journal of *Arthroscopy* published an article documenting that the combination of saline and [bupivacaine] inhibited cartilage cells after a two-hour period of exposure." (*Id*.) The defendant points out that the article also concluded that there was "[no] immediate need to stop the use of intraarticular bupivacaine." (*Id.* at 29.)

– In 1994, "the *Archives of Orthopaedic and Trauma Surgery* published an article that documented a study involving injection of saline into rabbit joints over a four-week period. The study shows that repeated exposure of saline was harmful to the cartilage." (*Id.* at 30.) The defendant points out that the study cautioned against "extrapolation from data in rabbit studies to man or other primates." (*Id.* at 31.) Also, in 1994, both *Arthroscopy* and the *Journal of Bone and Joint Surgery* published articles documenting that prolonged exposure (up to 20 hours) to certain so-called "irrigating" solutions could have an inhibiting or softening effect on cartilage in bovine and rats. (*Id.* at 31-32.)

– In 1997, "the journal *Acta Orthopaedica Scandinavica* published an article documenting a number of cases of chondrolysis following shoulder exposure to gentian violet," which is a dye used to mark the skin in surgery preparation. (*Id.* at 33.) In 2001, *International Orthopedics* published a case report documenting two more cases of chondrolysis following gentian violet exposure. (*Id.* at 35.)

– In 1998, the *Journal of Bone and Joint Surgery* "published a case report documenting chondrolysis in the knees of six patients who had chlorhexidine [a chemical antiseptic] applied to the joint during surgery." (*Id.* at 33.) In 1999, the same journal reported three more patients with the same condition following chlorhexidine exposure. (*Id.* at 34.)

– In 2002, *Arthroscopy* "published an article documenting the effect saline, morphine, and bupivacaine have on human cartilage." (*Id.* at 36.) While the article found some negative effect on cartilage, the defendant points out that the authors noted "a significant limitation of this study was that the cartilage selected [for the in vitro study] was from older patients with advanced osteoarthritis," and "we may reasonably believe the articular cartilage from middle-aged and younger patients may behave differently from that of older patients." (*Id.*) The study also concluded that tested combinations of bupivacaine and morphine did not have a "deleterious effect" on human articular cartilage. (Docket No. 153 Ex. 11 at 6.)

– The plaintiff also maintains that, in 2002, one article "expressed concern" that pain pumps "had not been independently investigated" and, in 2003, a series of presentations to professional surgeons raised the issue of chondrolysis. (*Id.* at 37-38.)

– In March 2004, "the *American Journal of Sports Medicine* (AJSM), a peer-reviewed medical journal, published an article [by Petty et al.] discussing [post-operative]

chondrolysis and making observations regarding the subject surgeries, including the use of pain pumps." (*Id.* at 38.) Dr. Trippel now claims that this was the first piece of "medical literature specifically identif[ying] an association between chondrolysis and pain pumps." (*Id.*) The article, which reported on three cases of chondrolysis, noted that a pain pump had been used in one of the three cases and concluded that the cause of the "rare and disturbing" disease was unknown but suggested that thermal energy, age, trauma, or "bioabsorbiable material within the joint" were possible factors. (Docket No. 153 Ex. 16.)

It is important to note that the Petty article stated that, heretofore, there had not been any case reports or literature linking this form of chondrolysis to routine shoulder surgery. (*Id.* at 1.) Moreover, there is no indication from the record that senior Stryker officials received any notification of any such problems with its pain pumps prior to 2005.

D. Dr. Kuhn

Dr. Kuhn began using pain pumps in 1994 while at the University of Michigan. At this time, he "established his protocol for using pain pumps . . . and never changed it thereafter." (Docket No. 157 at 6.) While it is not entirely clear what this "protocol" was, the record reflects that Dr. Kuhn generally used pain pumps without significant reservation to control post-operative shoulder pain.

Generally, Dr. Kuhn would generally review the "actual literature that comes with a particular device" prior to first using the device (and would trust that information), but he would not do so each time he used a device. (Docket No. 162 Ex. 65 at 63-64.) As to the pain pump, Dr. Kuhn's training for use of the pump did not rely on any sales representative or "Instructions for Use" provided by Stryker, and he does not recall any specific conversation with a Stryker representative about the use of the pump. (*Id.* at 63.) Dr. Kuhn was unaware of the specifics of the 510(k) approval process for the pain pumps at issue here. Dr. Kuhn has never been involved in determining whether to use a Stryker pain pump or some other pain pump; rather, he generally

used pain pumps and "simply use[d] whatever pain pump the facility happen[ed] to have in stock." (Docket No. 157 at 7.) Indeed, at the time of the plaintiff's surgery, Dr. Kuhn's nurse likely removed the pain pump from its packaging before bringing it to Dr. Kuhn in the sterile surgical area. (Docket No. 162 Ex. 65 at 64-65.)

While there is no indication that Dr. Kuhn actually reviewed the package insert that stated that the Stryker pain pump may be used at the "intraoperative" site, at his deposition, he testified that he believed that that language meant that he could use the pump at the site of the surgery, here, the joint space. (Docket No. 162 Ex. 65 at 72-73.) Dr. Kuhn testified that, had he received a warning about the risk of cartilage damage from the pain pump, he, in all likelihood, would not have used the pump in the plaintiff's surgery. (*Id.* at 68.)

While Stryker sales representatives knew that Dr. Kuhn was using the Stryker pump at Vanderbilt, there is no indication that Stryker, through its area sales representative or otherwise, made any effort to notify Dr. Kuhn about the 510(k) process or of the risk of chondrolysis. In 2006, Dr. Kuhn stopped using pain pumps entirely because he no longer trusted their pain-relieving effect.

D. Post-2004 Developments

In February 2005, Dr. Lonnie Paulos (who was a Stryker consultant at the time and is now one of the plaintiff's proffered experts) faxed a letter and wrote an e-mail to Stryker's Vice President of Endoscopic Device Sales (1) raising the concern that "the acidic effect of the anesthetics infused via pain pump" was responsible for a series of recent chondrolysis cases of which he had learned and (2) recommending labeling changes to the pain pumps and a three-month study. (Docket No. 176 at 40-42.) Again, there is no record of any complaint to Stryker

regarding chondrolysis from pain pump use prior to Dr. Paulos's February 2005 communication, although the plaintiff maintains that Paulos may have discussed his concerns with a Stryker sales representative shortly before he sent the February 2005 letter and e-mail. Nor is there any record of reports of chondrolysis or "other significant cartilage injury" to the FDA prior to the time of the plaintiff's surgery in November 2004. (Docket No. 157 at 4-5.)

Beginning in July 2005, Dr. Charles Beck, in podium presentations and in communications with Stryker, raised the association between chondrolysis and pain pumps. The plaintiff cites several additional articles and presentations between 2005 and 2006 raising the issue and notes (1) an October 2006 e-mail in which a Stryker representative noted that the company was receiving "2 to 3 messages a week"on the link between chondrolysis and pain pump use, and (2) a November 2006 Stryker internal memo proposing a study into the link. (Docket No. 161 Exs. 49-50.)

Since 2007, a series of articles in the medical literature has raised what can fairly be classified as "extreme caution" or "profound concern" about using pain pumps where the potential for chondrolysis is present. (*See* Docket No. 176 at 58.) The plaintiff maintains that the package label for the Stryker pain pump did not specifically warn about the risk of chondrolysis until May 2008. (*See* Docket No. 161 Ex. 59.) In November 2009, the FDA issued an advisory to healthcare professionals stating that "infusion devices are [not] approved for an indication of continuous intra-articular infusion. Health care professionals are encouraged . . . not to use these devices for continuous intra-articular infusion of local anesthetics after orthopedic surgery." (Docket No. 161 Ex. 60.) The plaintiff filed an updated FDA advisory issued in 2010 to the same effect. (Docket No. 162 Ex. 63.)

Again, on December 30, 2008, the plaintiff filed his Complaint in this case, claiming that Stryker was liable to him on strict liability, negligence and implied warranty grounds. (Docket No. 1 at 6.)

ANALYSIS

I. Summary Judgment Standard

Federal Rule of Civil Procedure 56(c) requires the court to grant a motion for summary judgment if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." If a moving defendant shows that there is no genuine issue of material fact as to at least one essential element of the plaintiff's claim, the burden shifts to the plaintiff to provide evidence beyond the pleadings "set[ting] forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "In evaluating the evidence, the court must draw all inferences in the light most favorable to the [plaintiff]." *Moldowan*, 578 F.3d at 374.

"'[T]he judge's function is not . . . to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). But "the mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient," and the plaintiff's proof must be more than "merely colorable." *Anderson*, 477 U.S. at 249, 252. An issue of fact is "genuine" only if a reasonable jury could find for the plaintiff. *Moldowan*, 578 F.3d at 374 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

II. The Plaintiff's Claims

A. Strict Liability

There is no dispute that the plaintiff's strict liability claims are governed by Comment K to Section 402A of the Restatement (Second) of Torts. (Docket No. 110 at 9; Docket No. 152 at 8.) That is, while strict liability usually attaches to manufacturers of defective or unreasonably dangerous products for the injuries caused thereby[6], Comment K imposes a well-recognized exception for "unavoidably unsafe products," such as prescription medical devices. *Harwell v. Am. Med. Sys.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994). An action in strict liability does not lie against the manufacturer of such a product if the product was "properly prepared and accompanied by proper directions and warning." *Id.*; Restatement (Second) of Torts, Section 402A, Comment K. Therefore, to the extent that the plaintiff has a viable strict liability claim, it would arise under a failure-to-warn theory.

Under the learned intermediary doctrine, a medical device manufacturer is required to "reasonably disclose[] to the medical profession all risks inherent in the use of the [device] which the manufacturer knew or should have known to exist." *Harwell*, 803 F. Supp. at 1299 (internal quotation omitted); *Nye v. Bayer Cropscience*, 2009 WL 3295137, *12 (Tenn. Ct. App. Oct. 14, 2009). When considering whether the manufacturer "should have known" about the risks of its product, the manufacturer is held to the standard of an expert in the relevant field at the relevant time. *See Martin v. Michelin N.A.*, 92 F. Supp.2d 745, 753 (E.D. Tenn. 2000).

There is nothing in the record to indicate that Stryker was actually aware of the risk of chondrolysis stemming from use of its pain pump at the time of the plaintiff's November 2004

[6]*See Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008).

surgery. The dispute comes down to whether Stryker "should have known" of this risk, or, in other words, had "constructive knowledge" of the risk and, therefore, should have warned about it. *See id.*

Stryker argues that, at the time of the surgery, there was no medical authority that suggested a link between use of the pain pump and chondrolysis, and, therefore, there was "literally no way" for Stryker to have warned about this risk by the time of the plaintiff's surgery. (Docket No. 110 at 11-12.) Stryker again points to Dr. Trippel's testimony in a prior case in which he stated that, even as of June 2005, there was not a single scientific article that attributed cartilage injury to the use of anesthetic – however the anesthetic was delivered. (*Id.*) As medical science had not begun to understand the risk allegedly presented by pain pumps by the time of the plaintiff's surgery, the defendant argues, strict liability cannot be imposed on the defendant here. (*Id.*)

The plaintiff argues that, "had Stryker performed a review of the scientific literature available at the time . . . it would have discovered that infusion of solutions into the joint space posed a danger of serious harm to articular cartilage." (Docket No. 152 at 2.) This research (and subsequent additional testing of the product) should have been sparked by, among other things, "the FDA's refusal to approve the pain pump for intra-articular use." (*Id.* at 5.) Instead of researching and testing its product, the plaintiff argues, Stryker chose a path of "willful ignorance," and it should not be rewarded with summary judgment for choosing that path. (*Id.*)

The plaintiff's position is unpersuasive. While the pre-2004 medical articles raise the general notion that the health of (usually animal) cartilage could be weakened by prolonged exposure to certain "foreign elements," it is a bridge way too far to say that Stryker – in the

context in which infusion pumps were broadly used and medically accepted without reservation – should have, prior to marketing the pain pump, culled through seven decades of literature, found the sporadic articles raising this concern, ignored all authority/evidence to the contrary, and then independently concluded that its pain pump could cause chondrolysis, particularly where no one in the medical community connected the destruction of cartilage to the use of pain pumps until after the plaintiff's surgery.

Again, the plaintiff argues that Stryker should have been "tipped off" to the risk by the FDA's repeated rejection of the proposed indication of the pain pump for use in the synovial cavity. (Docket No. 158 at 5.) There are problems with this argument. One, there is no indication that, in refusing to indicate the product for this use, the FDA was making any safety determination regarding using the product in this way; rather, the FDA was simply concluding that there was no medically cleared product that had a specific indication for use in the synovial cavity. Two, as the defendant repeatedly argues, the FDA did (twice) clear the pump for use, without limitation, at the "intraoperative" site – with nothing to suggest that, if the "intraoperative" site was at the synovial cavity, the pump was not indicated for use. Indeed, this was precisely the circumstance here, as Dr. Kuhn placed the pain pump at the site of the operation – the shoulder joint. (Docket No. 176 at 67.)

Finally, even if the defendant had interpreted the FDA's refusal to specifically indicate the pain pump for use in the synovial cavity as a "call to arms" on research in this area, it is entirely speculative to assert that anything would have changed in terms of the plaintiff's disease course. As discussed above, in the past five or six years, medical literature has gone from silence on a linkage between pain pumps and chondrolysis to strongly suggesting – but not confirming – a

linkage. (*See* Docket No. 153 Ex. 16; Docket No. 150 Ex. 7.) The argument that Stryker should have been alerted by the FDA's action in June 2001, and, then, over the course of the three years before the plaintiff's surgery, (1) independently discovered and confirmed the risk of chondrolysis and then (2) effectively notified physicians such as Dr. Kuhn (who had been relying on pain pumps without reservation for a decade or more) is not a credible position.

On any reasonable definition of the term, the risk of chondrolysis was not "knowable" at the time of the plaintiff's surgery in November 2004. Again, Stryker is tasked with the knowledge and understanding of an expert, but, at the time of the plaintiff's surgery, no literature drew a linkage between the condition that the plaintiff allegedly developed and devices of the type manufactured by the defendant. Simply put, no expert – at the relevant time – knew of the specific risk and, therefore, it is unreasonable to conclude that Stryker should have had constructive knowledge of that risk. Therefore, the plaintiff's strict liability claims fail.

As noted above, there are many similar cases currently being litigated, and it is worth noting that other courts have reached similar conclusions. Indeed, Stryker points to three other district court decisions granting summary judgment to the defendant manufacturer on nearly identical facts. *Phillippi v. Stryker Corp.*, 2010 WL 2650596, *2-3 (E.D. Cal. July 1, 2010)(rejecting nearly identical arguments regarding the 510(k) application and finding that the state of medical knowledge at the time of surgery (2005) did not dictate that Stryker should have warned about the risk of chondrolysis); *Meharg v. I-Flow Corp*., 2010 WL 711317, *3 (S.D. Ind. March 1, 2010)(finding no duty to warn on the part of the local anesthetic manufacturer as of February 2006); *Krumpelbeck v. Breg*, Case No. 1:09-00091 (S.D. Ohio Dec. 27, 2010)(Docket No. 181 Ex. 1 at 26-27)(finding issues regarding FDA compliance "immaterial" to plaintiff's state

law claims and finding that the duty to warn "line" "had not been reached" by the time of plaintiff's surgery in March 2005)).[7]

B. Negligence

The parties dispute whether Comment K applies to the plaintiff's negligence claims. The plaintiff argues that, for all products, the negligence inquiry considers: (1) whether the product was defective or unreasonably dangerous, and, if so, whether the defective or unreasonably dangerous condition "was the result of negligence in the manufacturing process or that the manufacturer or seller knew or should have known of the defective condition." (Docket No. 152 at 23 quoting *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976)). That is, in addition to demonstrating a defect, the plaintiff must also show that the defendant breached its duty of reasonable care. *Benson v. Tenn. Valley Elec. Co-op.*, 868 S.W. 2d 630, 636 (Tenn. Ct. App. 1993). Finally, the plaintiff must show that the defendant's breach of duty was the proximate and actual cause of the plaintiff's injury. *Leatherwood v. Wadley*, 121 S.W.3d 682, 693-94 (Tenn. Ct. App. 2003)).

The defendant points out that the Tennessee Products Liability Act (TPLA) "explicitly incorporates the strict liability standards of defect and unreasonable dangerousness as predicate burdens of proof to any cause of action for products liability, regardless of theory." (Docket No.

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[7]After the defendant filed the *Krumpelbeck* case with the court, the plaintiff filed *Koch v. Breg*, Case No. 08-4193 (D. S.D. Dec. 20, 2010), which involved a plaintiff who had shoulder surgery in August 2005. There, the court found that, while evidence supported the defendant's "position that it could not have reasonably foreseen the alleged fact that its pain pumps cause chondrolysis," a reasonable jury, relying on the 1985 article that tied bupivacaine to cartilage damage, could find an actionable failure to warn. (Docket No. 182 Ex. 1 at 7-8.) As noted above, the 1985 article explicitly stated that there was no need to stop the use of bupivacaine, and, for the reasons discussed above, the court respectfully disagrees with the decision reached in *Koch*.

174 at 5; *see* T.C.A. § 29-28-105(a)) In turn, Comment K "holds that a prescription medical device is neither defective nor unreasonably dangerous if it is manufactured appropriately and accompanied with adequate warnings." (*Id.*) Therefore, the defendant argues, the limitations imposed by Comment K should prevail over the plaintiff's claims, no matter the theory under which they are advanced. (*Id.*)

As can be seen from the parties' briefing, both approaches essentially lead to the same place. The plaintiff argues that "Stryker breached its duty of care (1) by failing to conduct safety tests and to research the medical literature, available prior to November 2004, demonstrating that introducing foreign substances to cartilage was dangerous. . . . (2) by failing to instruct physicians not to use its pain pump in the intra-articular space . . . (3) by failing to disclose the known fact that, because of a lack of safety data, the FDA excluded intra-articular use in the pain pump's general indication for intra-operative use . . . [and] (4) by failing to warn regarding the knowable danger posed by infusing cartilage with foreign substances, such as local anesthetics." (Docket No. 152 at 24-31.) Because there is no duty to "warn of an unknown," implicit in all of these allegations is that Stryker should have known about the chondrolysis risk associated with the pain pump and should have acted on that risk. *Suddeth v. Parks*, 914 S.W.2d 910, 914 (Tenn. Ct. App. 1995); *Novak v. U.S.*, 865 F.2d 718, 727 (6th Cir. 1989).

Again, because the court finds that it is unreasonable to conclude that the defendant had constructive knowledge of the link between chondrolysis and its pain pumps, at the time of the plaintiff's surgery, the assertions that the defendant breached the duty of care by not conducting more research/testing and by not warning doctors of risks associated with anesthetic infusions are

misplaced.[8] While it requires some repetition, for the sake of completeness, the court will discuss each alleged breach of duty in turn.

— Breach of Duty to Test/Warn of specific risk

Based upon the case law's silence on the issue, it is clear that there is no broadly recognized "duty to test" in Tennessee. Indeed, when the TPLA discusses "testing," it is in the context of instructing courts to consider whether the product was defective in light of "testing by other manufacturers . . . of similar products." See T.C.A.§ 29-28-105(b). The plaintiff has not come forward with any authority suggesting that a defendant *per se* breaches its duty of care by failing to test for the condition that eventually injured the plaintiff. *See Fulton v. Pfizer Hosp. Prods. Group Inc.*, 872 S.W. 2d 908, 912 (Tenn. Ct. App. 1993)(manufacturer is not an "insurer" of its products).

That said, the plaintiff cites a few (non-controlling) cases that have referred to the notion that a manufacturer is required to "test" its products (particularly medical products) to ensure that

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[8] Before reaching the breach-of-duty issues, the parties extensively briefed whether or not the pain pump was defective or unreasonably dangerous. The defendant primarily argued that the pain pump was not defective or unreasonably dangerous because the pain pump's "warning conformed to the state of the art when it was put on the market." (Docket No. 110 at 13.) Because the "state of scientific and technological knowledge available" at the time that the product was placed on the market is a key consideration under the TPLA in determining whether the product was defective, the defendant argues that its failure to warn about chondrolysis does not render the product defective. (*Id.* at 12 citing T.C.A. § 29-28-105(b)). The defendant also argued that the plaintiff had not put forward sufficient expert testimony to withstand summary judgment on the defect issue. (*Id.* at 14-16.) In response, the plaintiff argues that the pump "failed to conform to the state of the art," because, among other things, Stryker did not warn of infusion risks and did not conduct testing "to determine whether its pain pump was safe for intra-articular infusion." (Docket No. 152 at 9-15.) The plaintiff also maintains that he has offered the requisite expert testimony to proceed with a product defect claim. (*Id.* at 16-23.) Because the court finds that Stryker would not be liable under a negligence or warranty theory, even if the product were unreasonably dangerous or defective, it is not necessary to reach these issues.

the dangers associated with the product are discovered. (Docket No. 152 at 24-27; *citing e.g. George v. Celotex Corp.*, 914 F.2d 26, 28 (2nd Cir. 1990)(duty to test for "scientifically discoverable" risks); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 141 (3rd Cir. 1973)(defendants must test with "foresight appropriate to their enterprise" and, in that case, it was a jury question as to whether the defendants had done so).

Clearly, there is no broad (and prohibitively expensive) duty on the manufacturer's part to research and test for every possible risk that, with the benefit of hindsight, could be envisioned from use of the product. Indeed, such a requirement would, in many instances, eviscerate the distinction between strict liability and negligence. As implicitly recognized by the TPLA, a manufacturer's specific duty to test and research its product requires an exploration of the facts of each case. *See id.* Here, in contrast to *Hoffman* for instance, the defendant was not "try[ing] out" drugs on the public to determine whether they will "kill or cure." 485 F.2d at 141. Rather, the pain pump used well recognized and accepted infusion technology. The plaintiff's argument that – despite this – the defendant still should have tested the product for an unknown risk ignores its clear hindsight bias.

At the time that this product was marketed, no one knew of this specific risk, and it would not have been reasonable – at that time – to refer to a party as "negligent" for failing to conduct additional testing and research to explore this unknown risk. Consistent with this, it was not a breach of duty of reasonable care for the defendant to not "instruct physicians not to use its pain pump in the intra-articular space." (Docket No. 152 at 29.) Simply, because there was no way to reasonably know of this risk, it is not logical to argue that the defendant should have warned doctors about chondrolysis.

— Breach of Duty to Warn of Known Risks/Facts

Similarly misplaced are the plaintiff's claims that the defendant should have warned of "known" risks or facts, that is, the FDA's refusal to indicate the pain pump for use in the synovial cavity and the "knowable danger posed by infusing cartilage with foreign substances." (Docket No. 152 at 30-31.) At the time of the FDA action, there was no apparent reason to warn that the FDA had not specifically indicated the pain pump for use in the synovial cavity. The risk of chondrolysis was, at that time, unknown, pain pumps were generally used without reservation, and the FDA had broadly approved the pain pump for use intraoperatively, which, logically, could include use in the synovial cavity. In this context, there was no basis to reasonably anticipate that the defendant would have informed physicians that its 510(k) application as to an indicated use for the synovial cavity had not been granted.

And, again, given the context of the time and without knowing that the pain pump could cause cartilage destruction, it would not be reasonable to conclude that the defendant was negligent for failing to warn doctors regarding the risk of "infusing cartilage with foreign substances." While, spread out over the decades, there was some medical literature to suggest that cartilage could be weakened or softened by the continuous infusion of foreign substances, pain/infusion pumps were widely used in the medical community without issue. In this context, there was no reason for the defendant to have located this specific literature or warned physicians about it.

In light of all of this, there was no breach of duty here.

— Causation

However, even if there was a fact issue on the breach issue, the plaintiff's negligence

claim would still fail on the issue of proximate cause. For the plaintiff to prevail here, he would have to sufficiently show that Dr. Kuhn's decisions surrounding his use of the pain pump "were influenced by any representation which the defendant[] made or failed to make." *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000)("Both of the plaintiffs' implanting physicians were well experienced in the use of [the device]. Both . . . relied [entirely] upon their own knowledge and judgment in deciding to implant the devices into the plaintiffs. . . . Thus, the plaintiffs' claims . . . fail because they have failed to establish that, had additional warnings been given, the plaintiffs would not have sustained their injuries.")

Here, it is clear that Dr. Kuhn made the decision to use the pain pump entirely on his own. He had developed a protocol for using the pain pump as of 1994, and he continued to use the pain pump, without reservation, until 2006, when he stopped because he no longer believed in the effectiveness of the device. In using the pain pump here, Dr. Kuhn was simply using his medical training and his discretion; he believed in the pain pump, and, therefore, he used it. There is nothing to suggest that Stryker's conduct had any bearing on Dr. Kuhn's decision to use the pain pump one way or the other, and, therefore, the plaintiff's negligence claim fails on this additional ground.[9]

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[9]The plaintiff points to Dr. Kuhn's testimony that he, in all likelihood, would not have used the pain pump in November 2004 if he had known about the risk of chondrolysis. (Docket No. 152 at 32.) Of course at this time, no one had documented the specific risk of chondrolysis, and, as discussed above, the court will not charge Stryker will the responsibility for uncovering a heretofore unknown medical phenomenon. As the court stated in *Phillippi v. Stryker*, "it is without controversy that the decision to use Stryker's infusion pump in the fashion that it was used during Plaintiff's surgery was solely and exclusively Dr. Younger's, who received no direction or instruction from Stryker as to the placement of the catheter, the type of anesthetic utilized, the amount of anesthetic utilized, the rate at which the anesthetic was administered via the pump, or the duration of time during which the anesthetic was administered. Because all these variables were within the doctor's discretion, Stryker cannot be liable as a matter of law for

C. Implied Warranty

The parties spend little more than a few pages briefing the plaintiff's implied warranty claims. (Docket No. 110 at 18; Docket No. 152 at 35-36.) As discussed above, the TPLA makes clear that – whatever theory of liability claimed in a products liability action (negligence, warranty, strict liability, etc.) the plaintiff must show injury to person or property resulting from a defective or unreasonably dangerous product. T.C.A. § 29-28-102(6). A finding that a product was not defective or unreasonably dangerous forecloses an implied warranty claim under the TPLA. *Irion v. Sun Lighting, Inc.*, 2004 WL 746823, *18 (Tenn. Ct. App. April 7, 2004).

Likewise, a finding that the defendant's failure to warn was not the proximate cause of the plaintiff's injury forecloses the plaintiff's implied warranty/products liability claim. *Wood v. Danek Med.*, 1998 WL 665774, *6 (Tenn. Ct. App. June 17, 1998)(finding that physician's "independent decision" to use a medical device negated the proximate cause element of the plaintiff's failure to warn claim and necessitated the dismissal of the plaintiff's negligence, implied warranty, and strict liability claims); *Preston v. City of Manchester*, 1990 WL 125517, *12 (Tenn. Ct. App. Aug 31, 1990)(dissenting opinion generally discussing the notion that implied warranty actions are "first cousins" of negligence and strict liability actions and that they require a showing of proximate causation). The court's earlier finding that the risk here was not known or knowable and that the plaintiff cannot sufficiently demonstrate proximate causation forecloses the implied warranty claims.

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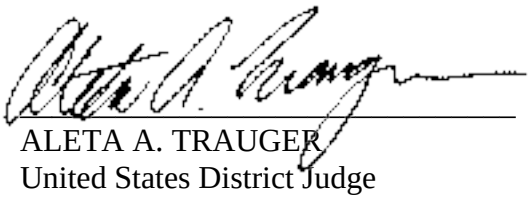
an injury which, assuming that medical causation were established, would be due solely to the doctor's decisions on these factors." 2010 WL 2650596, *3.

CONCLUSION

For the reasons discussed herein, the defendant's Motion for Summary Judgment will be granted, and this case will be dismissed. All other pending motions will be denied as moot.

An appropriate order will enter.



ALETA A. TRAUGER
United States District Judge